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IN THE CIRCUIT COURT, FOURTH JUDICIAL CIRCUIT, IN AND FOR DUVAL COUNTY, FLORIDA

CASE NO.: 2019-CA-2875
DIVISION: CV-B

JESSICA LYNN SWEAT-COLE,

Plaintiff,

v.

LOREN Z. CLAYMAN, M.D.,
LOREN Z. CLAYMAN, M.D., P.A.,
a Florida corporation,
ELANA CLAYMAN, and
ALLERGAN SALES, LLC,
a foreign limited liability company,

Defendants.
_____/

AMENDED COMPLAINT

The Plaintiff, **JESSICA LYNN SWEAT-COLE**, sues the Defendants, **LOREN Z. CLAYMAN, M.D.**, **LOREN Z. CLAYMAN, M.D., P.A.**, **ELANA CLAYMAN** and **ALLERGAN SALES, LLC, a foreign limited liability company**, and alleges the following:

GENERAL ALLEGATIONS

1. This is an action for damages in excess of $15,000, exclusive of attorney's fees, costs, and interest.

2. All conditions precedent to the filing of this action have been performed or have occurred.

3. At all times material hereto, the Plaintiff, **JESSICA LYNN SWEAT-COLE** (hereinafter "Ms. Sweat-Cole"), was and is a resident of, and permanently domiciled in, Maxville, Duval County, Florida.

4. All medical care and treatment rendered to Ms. Sweat-Cole upon which the claims set forth herein are based took place in Jacksonville, Duval County, Florida.

5. At all times material hereto, the Defendants, **LOREN Z. CLAYMAN, M.D.** and **ELANA CLAYMAN**, were and are residents of, and permanently domiciled in, Jacksonville, Duval County, Florida.

6. At all times material hereto, the Defendant, **LOREN Z. CLAYMAN, M.D., P.A.**, was and is a Florida Corporation, existing and operating under the laws of the State of Florida, and in fact doing business in Jacksonville, Duval County, Florida, to-wit: offering plastic surgery and aesthetic spa services and products to the general public. Clayman P.A.'s principal address is 1801 Barrs Street, Suite 200, Jacksonville, Florida 32204, and Clayman P.A. may be reached for service of process through its registered agent, Loren Z. Clayman, M.D., at 1801 Barrst Street, Suite 200, Jacksonville, Florida 32204.

7. The Defendant **ALLERGAN SALES, LLC** (hereinafter "Allergan") was and is a foreign limited liability company, with its principal place of business and permanent domicile at 2525 Dupont Drive, Irvine, California 92612.

8. Allergan is authorized to do business in the State of Florida, and has and is doing business in the State of Florida, to-wit: researching, testing, designing, developing, manufacturing, marketing, promoting, distributing, selling, or otherwise placing into the stream of commerce medical devices and/or pharmaceuticals, including but not limited to, Allergan Natrelle saline filled breast implants and warranties for same, in Jacksonville, Duval County, Florida.

9. Allergan may be reached for service of process in Florida through its registered agent, CT Corp. System, at 1200 South Pine Island Road, Plantation, Florida 33324.

10. Allergan's co-conspirators and joint venturers, whom Allergan aided and abetted in a fraudulent scheme, were: (i). Loren Z. Clayman, M.D. (hereinafter "Clayman Senior"); (ii). his son, Mark A. Clayman, M.D. (hereinafter "Clayman Junior"); (iii). Clayman Senior's wife, Elana Clayman (hereinafter "Elana Clayman") and (iv). their medical professional association, Loren Z. Clayman, M.D., P.A. (hereinafter the "Clayman Practice").

FACTUAL ALLEGATIONS

The Clayman Saline Breast Implant Warranty Scheme

11. Clayman Senior was first licensed as a medical doctor in the State of Florida on January 10, 1975. On December 31, 1976, he completed a residency in plastic surgery, and he began practicing in Jacksonville, Florida. Soon after establishing his plastic surgery practice at the P.A., he began performing breast augmentation surgeries. During the 1980's, a substantial portion of the breast augmentation procedures he performed were with silicone filled breast implants.

12. After the FDA prohibited the sale of most silicone implants in 1992, Clayman Senior began using saline filled implants exclusively.

13. As of the early 2000s, the Clayman Practice began marketing its breast augmentation practice to patients of modest means. To reach this population of potential patients, the Clayman Practice advertised extensively in free local discount publications such as *Mint Magazine*, *Money Pages*, and *Folio Weekly*; samples of these advertisements are attached and incorporated by reference as "Composite Exhibit A."

14. To attract patients of modest means, the Clayman Practice began charging less than any other plastic surgeons for augmentation mammoplasty procedures. Specifically, the Clayman Practice charged no more than $3,750 for an augmentation mammoplasty procedure

(breast augmentation); by contrast, most plastic surgeons in the Jacksonville, Florida community charged between $5,000 and $10,000 for a breast augmentation.

15. To reach this very low price point, the Clayman Practice did the following: performed procedures within its own offices rather than at a hospital or surgical center; performed procedures without the assistance of an anesthesiologist or qualified nurse anesthetist; set up two surgical rooms connected by a swinging door, so the surgeon could have two surgeries going at one time; performed breast augmentations in only 20 to 30 minutes, when most plastic surgeons take between one and two hours; purchased saline solution in large bulk bottles rather than single use surgical bags; and used the same make and model saline breast implant for every procedure because it was the cheapest. Indeed, after the FDA once again permitted silicone breast implants for breast augmentations, the Clayman Practice continued using saline breast implants exclusively because they were cheaper than silicone implants.

16. No later than the mid-2000s, Clayman Senior and/or Elana Clayman began repeatedly telling their breast augmentation patients that they had ruptured, deflated, or leaking saline breast implants, and that they needed to have removal and replacement surgeries as a result. However, Clayman Senior and/or Elana Clayman were lying to their patients; the breast implants were not ruptured, deflated, or leaking (not defective); and the removal and replacement surgeries they recommended were not necessary. Clayman Senior and/or Elana Clayman lied to their patients because they knew that most of them could not afford to pay for additional surgeries, but that by claiming that saline breast implants were ruptured, deflated, or leaking, they could seek to have the breast implant manufacturers pay for additional surgeries through their Warranties. After June 30, 2008, Clayman Junior joined the Clayman Practice and began practicing plastic surgery, including breast augmentations. He, too, began lying to his patients

about ruptured, deflated, or leaking saline breast implants, and he also began making an excessive or unusually high number of warranty claims for saline breast implants.

17. To make false warranty claims to Inamed/McGhan (which was later acquired by Allergan), the Clayman Practice and/or Elana Clayman had each patient and Clayman Senior or Junior sign a warranty claim form stating that the patient had a rupture, deflation, or leak that required a removal and replacement surgery, and assigning the benefits of the warranty to the Clayman Practice. The Clayman Practice and/or Elana Clayman had patients sign Allergan's claim forms *before* the surgeon had even performed the removal and replacement surgery to confirm that a rupture, deflation or leak had actually occurred. After the surgery, the Clayman Practice and/or Elana Clayman sent the completed warranty claim form and removed saline implant(s) to Allergan pursuant to the requirements of the Warranty.

18. Upon receiving the warranty claim paperwork and the returned breast implant(s) from the Clayman Practice and/or Elana Clayman, Allergan would then undertake a "Laboratory Analysis" on the returned breast implants to determine the cause of a claimed rupture/deflation/leak; after making the determination, Allergan generated a report of its findings.[1] Nearly every *Laboratory Analysis* report for saline filled breast implants returned by the Clayman Practice and/or Elana Clayman found no evidence of a "loss of shell integrity, resulting in implant rupture or deflation." Nevertheless, Allergan sent the Clayman Practice a check for the Surgery Money (either $1,200 or $2,400, depending upon the type of Warranty that applied) <u>for every warranty claim made by the Clayman Practice over a 15-year period</u>. As a

[1] One important reason the Clayman-Allergan scheme was undiscovered for a number of years was that Allergan did not as a matter of course provide patients with copies of their *Laboratory Analysis* reports.

result, Allergan funded thousands of harmful, unnecessary surgeries procured by the Clayman Practice's lies to patients.

19. From the *Laboratory Analysis* reports and the claim forms--signed jointly by Clayman Senior or Junior and each patient—Allergan knew two facts: First, Allergan knew that the Clayman Practice was lying to its patients about their need for unnecessary removal and replacement surgeries; second, Allergan knew that these lies were made for the purpose of procuring from Allergan, through the Warranty, the Surgery Money. In particular, the claim forms, signed by Clayman Senior or Junior and the patients, revealed to Allergan that Clayman Senior or Junior had told patients their implants were ruptured, deflated or leaking and needed to be surgically removed and replaced; the corresponding *Laboratory Analysis* reports, however, demonstrated to Allergan that Clayman Senior or Junior's representations to patients were false and intended to procure the Surgery Money for unnecessary removal and replacement surgeries. Armed with this knowledge, Allergan could have refused to pay the Surgery Money under the terms of the Warranty. Instead, Allergan paid the Surgery money to the Clayman Practice so that the Clayman Practice could "pocket" the Surgery Money for unnecessary removal and replacement surgeries.

20. When Clayman Senior and Elana Clayman first began pursuing the saline breast implant warranty scheme in the mid-2000s, the Clayman Practice purchased saline filled breast implants from both Allergan and Mentor, Allergan's primary American competitor in the manufacture of breast implants (Mentor was later acquired by Johnson & Johnson). When Mentor received a high number of warranty claims relative to the number of implants purchased by the Clayman Practice, Mentor's quality assurance department (hereinafter "Mentor QA") contacted its regional sales manager and advised him that the Clayman Practice had made

approximately 40 warranty claims in the preceding year, which amounted to 30% of all saline breast implants the Clayman Practice purchased from Mentor. Mentor QA considered this percentage to be excessive and indicative of fraud. Mentor QA asked its regional sales manager to visit the Clayman Practice in person and demand an explanation for the excessive number of saline breast implant warranty claims.

21. Thereafter, the regional sales manager went to the Clayman Practice and told a female employee that he needed to discuss the excessive saline breast implant warranty claims with Clayman Senior. In response, the employee said, "I told him he was going to get in trouble if he kept doing this." When the employee went to Clayman Senior's office to tell him that the regional sales manager wanted to speak with him, she returned soon afterward and told the regional sales manager that Clayman Senior did not wish to speak with him. In response, the regional sales manager told the employee that Mentor would no longer sell breast implants to the Clayman Practice. Since this incident, Allergan has been the exclusive supplier of breast implants to the Clayman Practice.

22. In contrast to Mentor, Allergan has never confronted Clayman Senior about his excessive warranty claims for saline breast implants, even as the number of warranty claims to Allergan has increased exponentially. A copy of a bar graph showing the Clayman Practice's saline breast implant warranty claims to Allergan between January 1, 2000 and December 31, 2015 is attached and incorporated by reference as "Exhibit B" to this *Complaint*.

23. According to Allergan's own studies, the rate of spontaneous deflations for Natrelle saline filled breast implants is approximately 2.7% to 6.8% at 5 years, and approximately 10% to 13.8% at 10 years, which amounts to an average deflation rate of 1.2% for each year after implantation.

24. By comparison, between January 1, 2008 and December 31, 2015, Allergan sold the Clayman Practice **11,082** pairs of saline breast implants. During that same time period, the Clayman Practice made **5,118 warranty** claims for saline breast implants, which amounts to **a failure rate of 46%**.

25. Allergan had a deep financial motivation for paying the Clayman Practice's 5,118 warranty claims. Between January 1, 2008 and December 31, 2015, the Clayman Practice purchased 11,082 pairs of saline breast implants from Allergan, which makes the Clayman Practice one of Allergan's top 10 breast implant customers in Florida. Furthermore, the Clayman Practice purchased a host of other aesthetic products from Allergan, including the following: Botox, Latisse, Juvederm, Kybella, SkinMedica, Vivate, and CoolSculpting (a product marketed by Zeltiq Aesthetics, which is a subsidiary of Allergan). As the above-noted print advertisements from the Clayman Practice show ("Composite Exhibit A"), the Clayman Practice is essentially a "one supplier shop."

26. The Clayman Practice is a Diamond Level member of the Allergan Partner Privileges program for Allergan Aesthetics products (i.e., Natrelle, Botox, Latisse, Juvederm, Kybella, SkinMedica, Vivate, and CoolSculpting). The Allergan Partner Privileges program provides members with rebates, sales growth rewards, a special online physician locator listing, priority customer service line access, preferred shipment status, and certificates and status displays.[2] Indeed, when a nurse employed by the Clayman Practice asked Clayman Senior why he believed Allergan would keep paying his high volume of warranty claims without question,

[2] *See,* https://www.allergannetwork.com/components/app/content/pdf/APP2.0-Customer-FAQ.pdf.

Clayman Senior told her, "I know they're going to pay them all because I'm a Diamond Level partner."

27. Hence, even though Allergan knew that the Clayman Practice was lying to its patients about leaking, ruptured or deflated implants, that the Clayman Practice was performing unnecessary removal and replacement surgeries, and that the Clayman Practice was making false warranty claims for its saline breast implants, Allergan paid millions of dollars in false warranty claims to the Clayman Practice because it was making so much money in total sales of aesthetic products from the Clayman Practice.

28. Other plastic surgeons report that in response to their saline breast implant warranty claims, Allergan demanded further proof that the claimed ruptures, deflations, or leaks were not the result of actions by patients or surgeons, even though the other plastic surgeons made fewer than 5 saline breast implant warranty claims per year. The key distinction between these other plastic surgeons and the Clayman Practice is that the other plastic surgeons were not "one supplier shops," and they purchased their aesthetic products (including saline breast implants) from more than one supplier.

Allergan's Warranty through which Allergan Knowingly Funded

the Clayman Practice's Unnecessary, Harmful Surgeries

29. With all Natrelle breast implants, Allergan includes its "ConfidencePlus Warranty." According to its own literature, Allergan's Warranty applies to all FDA-approved Natrelle breast implants, provided the implants were used as intended and as directed, by qualified and licensed surgeons. However, the Warranty only applies to cases of:

- Loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention
- Capsular contracture (Baker Grade III/IV) with *Natrelle* Gel implants that requires surgical intervention

30. There are two versions of the Warranty: Standard and Premier. The Premier Warranty costs an additional $100 with each newly purchased pair of implants, and $200 after a replacement under the Warranty; the Standard Warranty comes at no additional cost with each newly purchased pair of implants, but costs an additional $100 after a replacement under the Warranty. The Standard Warranty provides, among other things, for a lifetime replacement of the ruptured implant and, for ten years, the replacement of the contralateral implant.[3] The Premier Warranty provides, among other things, for lifetime replacement of both ruptured and contralateral implants. The Standard Warranty initially comes with Natrelle implants free of additional cost, and costs $100 in the event of revision surgeries under warranty.

31. For purposes of this case, the critical coverage under both Warranties was the amount reimbursed for the cost of replacement/revision surgery (the "Surgery Money"). Under the Standard Warranty, if the originally provided implants were ruptured or otherwise deemed defective under the Warranty, then Allergan would not only provide replacement implants, but it would also provide $1,200 of Surgery Money for the cost of removing and replacing the patient's implants. Under the Premier Warranty, Allergan provided $2,400 of Surgery Money for the cost of replacement/revision surgery.

32. In relation to patients of the Clayman Practice, the Surgery Money provided by Allergan went not to the patient who purchased the Warranty, but to the surgeon performing the

[3] At first, only Natrelle Style 163 saline filled implants had lifetime replacement for contralateral breast implants; other Natrelle saline filled implants had only a 10 year warranty for contralateral implants. Beginning June 1, 2009, the Standard warranty was changed to provide for the lifetime replacement of contralateral breast implants for all Natrelle saline filled implants.

removal and replacement surgery, i.e. the Clayman Practice. In Ms. Sweat-Cole's case and the cases of the Clayman Practice's other breast augmentation patients, the surgeons at the Clayman Practice pocketed the Surgery Money, which was funneled through Allergan's Warranty, and used the Surgery Money to perform thousands of unnecessary surgeries that harmed their patients. The surgeons at the Clayman Practice and Elana Clayman repeatedly lied to their patients, including Ms. Sweat-Cole, telling them that the original implants were ruptured, deflated, or leaking and that, as a result, they needed surgery to remove and replace their purportedly defective saline breast implants. Allergan knew about these lies, and the company substantially assisted, conspired with, and engaged in a joint venture with the surgeons' fraudulent scheme by funding the unnecessary, harmful surgeries by directly paying the Surgery Money to the Clayman Practice and/or Elana Clayman.

33. Since acquiring McGhan/Inamed, Allergan devised an "off-balance-sheet" method of paying warranty claims for Natrelle saline filled breast implants. Specifically, to the best of the undersigned attorney's information and belief, Allergan pays breast implant warranty claims through Del Mar Indemnity Company, LLC, a captive insurance company created and owned by Allergan.[4] When a manufacturer such as Allergan creates a captive insurance company, the manufacturer is provided a means of reclassifying otherwise taxable income from across its various divisions and subsidiaries as "premium payments" that go to the captive insurance company. The formerly taxable income that is reclassified as "premiums" then accumulates within the captive, making it, essentially, a very large "slush fund." In the event that the manufacturer uses the captive insurance company to pay a "loss," such as a warranty payment, the loss is not reflected in Allergan's balance sheets or filings with the Securities and

[4] *See*, https://opencorporates.com/companies/us_hi/206243D1.

Exchange Commission. In addition, because the captive is not a third-party company, Allergan is free to manipulate the claims payment process without outside interference.

Allergan's Similar Course of Conduct during the Same Period of Time in which the Company Paid Physicians to Use Their Products

34. The Clayman saline implant warranty scheme is not the first time Allergan has been implicated in a scheme whereby the company bribes physicians to purchase the company's products, as Allergan has been implicated in violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), at least six times, resulting in Allergan paying a total of $1.089 billion in criminal penalties and civil settlements.

35. The Anti-Kickback Statute prohibits anyone from

> knowingly and willfully offer[ing] or pay[ing] remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> …
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program[5]…

42 U.S.C. §1320a-7b(b)(2).

[5] Because the Clayman Practice's patients paid for their breast augmentation procedures with cash (not under a Federal health care program), the Anti-Kickback Statute does not apply to the Clayman scheme, and Plaintiff asserts no claim under the Anti-Kickback Statute. Plaintiff, however, alleges the facts concerning Allergan's conduct under the Anti-Kickback Statute to show this Court that it is quite plausible that Allergan, consistent with its past criminal conduct, engaged here in criminal conduct by conspiring with, substantially assisting, and jointly venturing with the Clayman Practice to perpetuate fraud upon its patients.

36. Over the past eight years, Allergan was involved in the following:

A. **September 1, 2010**, Allergan was forced to pay $600 million in settlement of criminal and civil complaints that included allegations of providing free physician workshops and dinners, paying physicians to attend "advisory boards" promoting off-label uses, and created Alphamedica, which administered a speakers bureau that paid physicians $1,000 to allow sales representatives to shadow them at work.[6]

B. **September 15, 2010**, Allergan's Forest Laboratories division was forced to pay a $313 million settlement of criminal and civil complaints that included allegations of cash payments to physicians that the company described as "grants" and "consulting fees," expensive meals, and lavish entertainment to physicians to induce them to prescribe the drugs Celexa and Lexapro.[7]

C. **October 29, 2015**, Allergan's Warner Chilcott division was forced to pay a $125 million settlement in a case that included allegations of violations of paying doctors speaking fees to induce them to prescribe the drugs Asacol, Actonel, and Loestrin.[8]

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[6] *See*, https://www.justice.gov/opa/pr/allergan-agrees-plead-guilty-and-pay-600-million-resolve-allegations-label-promotion-botox; https://www.cbsnews.com/news/how-allergan-sponsored-a-history-of-sausages-to-promote-botox-illegally/.

[7] *See*, https://www.justice.gov/opa/pr/drug-maker-forest-pleads-guilty-pay-more-313-million-resolve-criminal-charges-and-false.

[8] *See*, https://www.wsj.com/articles/allergan-unit-to-plead-guilty-to-fraud-pay-125-million-1446139657/?mod=mktw.

D. **December 15, 2016**, Allergan's Forest Laboratories division was forced to pay a $38 million settlement in a case that included allegations of paying kickbacks to physicians to induce them to prescribe the drugs Bystolic, Savella, and Namenda.[9]

E. **June 29, 2017**, Allergan was forced to pay a $13 million settlement in a case involving allegations of providing valuable business consulting services, continuing medical education, and other valuable services to physicians to induce them to prescribe Allergan eye care products including Restasis, when other less expensive treatment alternatives were available.[10]

F. **Pending case**, *U.S. ex rel. Wood v. Allergan, Inc.*, civil complaint includes allegations that Allergan provided "customer care kits," office supplies, and over $100 million in free drug samples to targeted physicians to induce them to prescribe Allergan drugs.[11]

37. Allergan's previous conduct demonstrates that its involvement in the Clayman breast implant warranty scheme was and is part of a larger course of conduct whereby the company's marketing plan includes bribing physicians.

Jessica Lynn Sweat-Cole

38. Jessica L. Sweat-Cole first presented to the Clayman Practice for a breast augmentation consultation in April of 2007. At the time, she wore an A cup bra and had no

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9 *See*, https://www.justice.gov/opa/pr/forest-laboratories-and-forest-pharmaceuticals-pay-38-million-resolve-kickback-allegations.

10 *See*, http://www.pietragallo.com/library/files/nevyas_allergan_press_release_final.pdf.

11 *See*, 246 F.Supp.3d 772 (S.D. N.Y. March 31, 2017).

sagging. She reported to Clayman Senior that she wanted to be a large C or small D cup. Clayman Senior performed a very brief physical examination of her breasts without taking measurements, and with no female staff members in the room with him. Clayman Senior told her, "I'll make you look like a fucking million dollars." He then showed her a book of photographs of women Clayman Senior described as "older women who wanted to get freaky."

39. Ms. Sweat-Cole underwent the planned surgery in April of 2007, and she was satisfied with the results at the time, as she was a large C or small D cup and her incisions were at the inframammary folds.

40. In 2009, Ms. Sweat-Cole woke up one morning and discovered her left breast had become flat. She called the Clayman Practice and made an appointment for a follow up examination. Upon presenting to the office again, Ms. Sweat-Cole was examined by Clayman Senior without a female staff member present. After performing his physical examination once again without taking any measurements, Clayman Senior said she had a "pinhole" leak at her left breast implant and needed to have both of her implants removed and replaced. Clayman Senior promised to perform the revision surgery at no charge to her.

41. After Ms. Sweat-Cole presented for her second breast surgery with Clayman Senior, she was given anesthesia in the operating room. However, during the procedure she woke up and became aware of pushing and tugging. Clayman Senior told her to close her eyes and "go back to sleep." After the surgery, she discovered that he had put in larger breast implants, leaving her a cup size DD, which she had not asked to be.

42. In 2010, Ms. Sweat-Cole returned to Clayman Senior and complained that her left breast implant had migrated to her arm pit, and that she had no cleavage. After a very brief examination with no measurements or female staff members present, Clayman Senior told her

there was something wrong with her left breast implant, and that she should "stop having such kinky sex." He recommended another revision surgery in which he would remove and replace both of her implants at no charge to her because "Allergan would pay."

43. Ms. Sweat-Cole presented for her third breast surgery that same year. During the procedure she woke up again and began singing. In response, Clayman Senior told her that he was going to "stop playing music when [she was in the room] because [Ms. Sweat-Cole] sang too loud." After the surgery, Ms. Sweat-Cole discovered that Clayman Senior made new incisions at her areolas rather than using the inframammary folds, as he had done previously. He had also made her a DDD cup even though she had never asked to have larger breasts. From then on, she had problems with pain at her breasts. Further, her right breast became infected at the site of his incisions, and she had to take antibiotics.

44. In 2011, Ms. Sweat-Cole's left breast became smaller than the right breast. Once again, she returned for another examination by Clayman Senior, who told her "the bag [was] leaking." Ms. Sweat-Cole asked Clayman Senior why her left breast kept "leaking." In response, he told her, "Don't worry about it, it's not your problem; we'll fix it." Ms. Sweat-Cole told Clayman Senior that she was afraid of having another surgery, as she woke up in two of her previous three breast surgeries. Clayman Senior told her not to worry because he would give her valium to prevent her from waking up. Nevertheless, during this fourth breast surgery, she woke up as Clayman Senior was closing her incisions.

45. On January 27, 2014, Ms. Sweat-Cole presented once again to Clayman Senior with complaints that one breast was smaller than the other, although this time it was the right that was smaller. After examining her, Clayman Senior told her that she had a leak and that he needed to remove and replace both of her implants. Clayman Senior failed to document a

physical examination or his findings and recommendations for this visit in any follow up notes. A surgical estimate prepared on January 27, 2014 states that she needed to have a procedure to remove and replace her implants bilaterally because her right breast was "smaller."

46. Mysteriously, there are two separate entries for January 27, 2014 in the patient follow up ledger for Ms. Sweat-Cole. The first entry is very brief and states, "Consultation for implant change in size & shape (right)." The second entry is more detailed and states the following:

> Consult for Rt. leak—major change in shape of Rt breast; [complains of] ripples & [decrease in size]. She denies any trauma but does perform in Barrell Racing & had recent Rt. shoulder surgery. Thinks breasts sag, discussed areola incision to assist in symmetry because of severe rib prominent due to scoliosis. Wants larger, so both implants will be replaced/discussed asymmetry/cap. Cont./infection. Doesn't want anchor scar of mastopexy. Will always have some asymmetry due to scoliosis.

In her narrative, Ms. Sweat-Cole reports that she never discussed having scoliosis with Clayman Senior, and that no physician has ever told her that she has scoliosis, nor does she have any objective evidence of scoliosis on numerous X-rays and MRIs taken for other conditions.

47. On February 24, 2014, Ms. Sweat-Cole presented for her fifth breast surgery with Clayman Senior. In the surgical intake paperwork, Ms. Sweat-Cole wrote that one breast was bigger than the other, one breast sagged, that it was hard for her to find bras, and that she wanted "more cleavage." Employees or agents of the Clayman Practice had Ms. Sweat-Cole sign a surgical consent form that stated she was having a "Bilateral Re-Augmentation Mammoplasty." A preoperative photograph taken that day demonstrates she did not have a rupture, deflation or leak at either of her breasts.

48. In the operative report dated February 24, 2014, Clayman Senior documented that upon dissecting down to the right implant capsule, the implant was "found to have a leak at the

valve with tissue present and partial delamination of the valve." Furthermore, he documented that a "small amount of liquefied hematoma was found within the pocket with a large capsular tear involving the entire lateral and inferior aspects of the capsule identified [sic], consistent with some form of injury." The left implant was found intact. Both implants were removed and replaced with Allergan Natrelle Style 68 Medium Profile 360cc saline breast implants. Clayman Senior failed to document how much saline he used to inflate the implants other than that they were "inflated to their optimal capacity to give the patient her desired look." According to the OR Record, the entire procedure took only 29 minutes to complete. In her narrative report, Ms. Cole-Sweat denies that she experienced any trauma before her right breast became smaller than the left breast.

49. Before the surgery on February 24, 2014, employees or agents of the Clayman Practice had Ms. Sweat-Cole sign an Allergan breast implant warranty claim form that stated she had a deflation, rupture, or leak that caused her to have to undergo a removal and replacement surgery (the first page of the warranty claim form is missing from the medical records). Pursuant to Allergan's breast implant warranty, Clayman Senior signed the claim form and returned it with the removed implants to Allergan. On May 1, 2014, employees or agents of the Clayman Practice received a check from Allergan in the amount of $1,200.

50. On March 10, 2014, Ms. Sweat-Cole returned to the Clayman Practice for her first post-surgical follow up visit after her fifth breast surgery. At that time, she complained that one of her breasts was fuller/bigger than the other. Clayman Senior did not document a physical examination or his recommendations for further treatment to Ms. Sweat-Cole in light of her ongoing complaints.

51. On June 6, 2017, Ms. Sweat-Cole returned to the Clayman Practice with complaints that her left breast was smaller than her right breast, that her right nipple was collapsed, and that her left nipple was "hard as a rock." In an intake form of that date, Ms. Sweat-Cole wrote that she was "having problems" with her nipples, that her left breast was "all over the place and smaller," and that [she could] feel the bags."

52. In his *Consultation for Breast Reduction/Mastopexy/Augmentation* dated June 6, 2017, Clayman Senior documented that her goals were to "increase breast" "Lt. breast." He further writes that she would be undergoing further treatment in the form of an "Internal lift" "LT" and "Breast Adjustment – Incr." A surgical estimate prepared that same date stated that she would be undergoing a "Left Revision" at no charge to the patient.

53. On June 23, 2017, Ms. Sweat-Cole presented to the Clayman Practice for her sixth breast surgery. In the surgical intake form, Ms. Sweat-Cole wrote that her left breast was "sagging," that she could "feel nipples in bags on both," and that her right breast implant was "still hard." She also wrote that she was "350cc" and that she would "like 375cc if possible." Below this writing, it says "correction 360 to 400 cc." Ms. Sweat-Cole states that she did not write the "correction" on the form. Employees or agents of the Clayman Practice had Ms. Sweat-Cole sign a surgical consent form that stated she would be having a Left breast adjustment." However, the word "Left" is crossed out and under it, someone other than Ms. Sweat-Cole wrote "Bilateral." A preoperative photograph taken that day demonstrates that she did not have a rupture, leak or deflation at either of her breast implants.

54. In the operative report dated June 23, 2017, Clayman Senior documented that he added 75cc of saline to her right breast implant and 150cc to the left. Further, he documented

that the capsule on the left was "plicated over the dome with 3-0 mersilene sutures to assist with additional lift as requested."

55. On July 5, 2017, Ms. Sweat-Cole returned to the Clayman Practice for her first post-surgical follow up after her sixth breast surgery. At that time, she complained that her left breast still did not feel right, and that she could "hear the saline." Clayman Senior failed to document a physical examination or his recommendations for further care.

56. According to the medical records, on July 27, 2017 Ms. Sweat-Cole returned because she wanted an increase in the volume of her left breast implant. A surgical estimate recites that she would be undergoing a "Left adjustment" at "No charge."

57. On August 10, 2017, Ms. Sweat-Cole presented to the Clayman Practice for her seventh breast surgery. In the surgical intake form she wrote the following:

1. fix my left smaller sagging hurts
2. Can we replace both make the same.

58. On August 10, 2017, before the surgery, employees or agents of the Clayman Practice had Ms. Sweat-Cole sign a surgical authorization form acknowledging that she would be undergoing a procedure in which Loren Z. Clayman would "Adjust left breast – Saline increase exploration of lt breast implant." A preoperative photograph taken that day demonstrates that she did not have a rupture, deflation or leak in either of her breast implants.

59. In the operative report dated August 10, 2017, Clayman Senior documented that upon dissecting down to the left breast implant capsule, he injected 100cc of saline into the implant, bringing the total amount of saline in the left breast to 650cc, almost twice the recommended volume for a 360cc moderate profile implant.

60. Ms. Sweat-Cole presented to the Clayman Practice on August 21, 2017 for her first follow up visit after her seventh breast surgery. In the follow up note Clayman Senior failed

to document a physical examination or any discussion about his plan going forward. All that the note recites is that Ms. Sweat-Cole complained about a "burning feeling in left" and "swelling again."

COUNT I – CLAYMAN DEFENDANTS' MEDICAL NEGLIGENCE

61. Ms. Sweat-Cole re-alleges and incorporates by reference paragraphs 1 through 60.

62. At all times material, Loren Z. Clayman owed Ms. Sweat-Cole a duty to exercise that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, was recognized as acceptable and appropriate by reasonably careful physicians caring for a patient such as Ms. Sweat-Cole.

63. On or between July 18, 1991, and September 12, 2014, Loren Z. Clayman and/or Clayman PA fell below the accepted and/or applicable standard of care in the treatment of Ms. Seymour in one or more of the following ways:

a. Failing to properly document Ms. Sweat-Cole's medical and surgical care. The quality of the medical records are, at best, poor and completely inadequate throughout Ms. Sweat-Cole's care. The operative records do not contain sufficiently detailed descriptions of the indications for the procedures performed or sufficiently detailed descriptions of what exactly was done by Clayman Senior during the surgeries. None of the consultations or follow-up care contains any direct documentation by Clayman Senior of their encounters. Specifically, there is no record of discussion with her and counseling with regard to her goals or complaints. Also, the records do not contain a detailed description of her complaints, her desired goal, a detailed past medical history, past surgical history, or current medications. At a minimum, documentation should reflect the patient's subjective concerns, a review of pertinent medical history,

physical assessments including direct measurements, detailed documentation of the informed consent process, and a synopsis of findings leading to the surgical recommendation;

b. Failing to maintain Ms. Sweat-Cole's medical and surgical records as required by law. Despite repeated medical records requests sent to Clayman Senior's office, he failed to release his office records regarding Ms. Sweat-Cole for the time period of April 2007 through 2011. The documentation provided by Ms. Sweat-Cole clearly demonstrates that she had surgery; and the documentation matches medical records received for other similar lawsuits filed against Clayman Senior. Similar to his previously documented, universally poor documentation noted in said malpractice suits, this refusal to release medical records in an obvious attempt to obfuscate the truth regarding his practice of medicine and care of his patients;

c. Failing to have an informed discussion with Ms. Sweat-Cole about her options for breast implant surgery. Specifically, there were no discussions regarding implant type, pocket location, incision location, or implant size;

d. Failing to perform appropriate pre-surgical planning for breast implant surgery. No measurements were taken of Ms. Sweat-Cole's breasts, nor were there any discussions about her goals, her concerns, or the risks of surgery. She was also not given an opportunity to try on different size implants and have a documented discussion regarding incision placement, tissue plane (pre/subpectoral), implant type, and implant size. Additionally, no basic measurements of her breast dimensions were taken to appropriately guide and help select the optimal implant size. There is also no documentation of any breast measurements that would have helped a prudent surgeon

pick an appropriately sized implant for this patient based on commonly accepted dimensional planning concepts. There is no documented discussion regarding implant volume or evidence that there was an attempt to size the patient appropriately prior to proceeding with surgery;

e. Failing to properly document with photographs the appearance of Ms. Sweat-Cole's breasts before and after each surgery. The photographic documentation in Ms. Sweat-Cole's medical records is also inadequate or nonexistent. At the very minimum, antero-posterior, lateral and oblique views should be obtained. Standardization of photo background and lighting is also important and considered standard of care as it allows not only a means of further objective assessment of the problem, but also a means of comparison over time. The few photos in the records are poorly reproduced "Polaroids" that only show a frontal view from different depths and perspectives. The lack of adequate, standardized photographic documentation is very likely deliberate so that Loren Z. Clayman can continue to claim evidence of implant deflation when no such evidence exists. This lack of documentation is consistent with his deliberate attempt at obfuscation by not releasing the patient's medical records between April 2007 and 2011;

f. By mismanaging every aspect of Ms. Sweat-Cole's care, treatment, and surgery. Throughout multiple breast revision surgeries, Ms. Sweat-Cole continued to have problems with pain, implant hardness, implant rippling/visibility, and aesthetic results, especially with asymmetry of breast size, shape, and position. She was justifiably unhappy with the appearance of her breasts despite the repeated surgeries. Moreover, she

will require additional surgery just to try to correct the problems created by Clayman Senior;

g. By failing to perform revision breast augmentation procedures with appropriately sized, silicone gel filled implants, a proper site change to a submuscular plane, an inframammary approach, and proper anesthesia with some level of muscle paralysis, which would have more likely than not have resulted in an acceptable aesthetic outcome and resolution of Ms. Sweat-Cole's complaints to include pain, hardness, and implant visibility, rippling, and palpability;

h. By failing to place her implants in an appropriate submuscular pocket to address her concerns regarding an unnatural appearance, implant visibility, and implant hardness. It is very likely that the implants were difficult to position under the pectoralis major muscle due to inadequate muscle paralysis. Subpectoral implants may be placed under intravenous sedation provided that a proper pectoralis block is performed to adequate relax the muscle in combination with rib blocks for optimal pain control. There is no evidence that this was performed during any of Ms. Sweat-Cole's surgeries, contributing further to her unnatural breast appearance, breast hardness, and disappointing cosmetic result. The inadequate intravenous sedation during Ms. Sweat-Cole's procedures more likely than not lead to an inadequate subpectoral plane and pocket development, and likely caused or contributed to the implants being malpositioned. General anesthesia should have been considered for the revisionary procedures because they were significantly more involved than her initial breast augmentation procedure. More likely than not, Clayman, Senior took into account the limitations of intravenous sedation when he performed the revision surgeries, and there

was no legitimate medical justification for choosing intravenous sedation administered by a registered nurse for these procedures. It appears that Clayman Senior chose this approach merely to control costs;

i. By failing to use an appropriate type and quality of anesthesia for Ms. Sweat-Cole's initial augmentation, as well as in the subsequent removal and replacement procedures. Clayman Senior used the sedation protocol of ketamine and versed, which was administered by a registered nurse and not a certified registered nurse anesthetist (CRNA). This is significant, as the difference between a CRNA and a registered nurse is the ability to manage an airway during the procedure. The lack of presence of someone who is trained to manage an airway under sedation leads to significant under-sedation. In this case the patient was under-sedated for the initial procedure and all subsequent removal and replacement surgeries. Intravenous sedation should be deep enough to adequately perform the procedure without the patient waking up during the procedure or experiencing intraoperative pain. The patient reported that she woke up during Clayman Senior's procedures, had nightmares and experienced post-operative nausea and vomiting. Moreover, Clayman Senior continued to use basically the same anesthetic regimen even though the patient continued to experience these anesthetic complications;

j. By failing to appropriately assess and counsel Ms. Sweat-Cole about realistic and safe recommendations that would address her concerns and obtain her goals. Ms. Sweat-Cole's complaints and persistent deformities were set in motion by a combination of poor preoperative counseling and assessment, as well as poor to non-existent surgical planning and preparation, and poor intraoperative execution of the first surgery and all subsequent surgeries. Initially, a properly executed dual plane breast

augmentation with appropriately sized silicone gel-filled implants would have more likely than not to have delivered the aesthetic result she desired. Instead, she was left with a continuing deformity and poor aesthetic appearance that included overfilled saline implants in a subglandular position, breast size asymmetry (left > right), position asymmetry with the left breast sitting higher than the right, and a flat/boxy lower pole. A proper repair of the poor outcome caused by Clayman Senior's initial procedure would have included a site change with smaller silicone gel filled implants placed through an inframammary incision. Clayman Senior failed to provide or even offer such a procedure to Ms. Sweat-Cole, with the result being her continuing breast deformities and the need for subsequent surgery;

k. By using a poorly placed superior areolar incision during her revision surgery in 2010. Evidence based medicine and numerous articles in the plastic surgery literature have demonstrated increased rates of capsular contracture with the use of an areolar incision. In Ms. Sweat Cole's case, she had an existing inframammary incision that would have been adequate for any revisionary procedure. Using the pre-existing inframammary incision would have prolonged the surgical time and made accessing the saline valve more difficult, and as a result, Loren Z. Clayman elected to create a new, visible incision that was poorly placed within her areolas, but that saved him time at the expense of the patient. As a result, she has a very visible incision with loss of areola pigment. Clayman Senior's lack of attention to detail and "need for speed" resulted in an incision placed within the areola instead of along the junction of the pigmented areolar skin with normal appearing skin or utilization of an existing inframammary incisions as

recommended by current best practices within the widely accepted plastic surgery literature;

l. By repeatedly operating on Ms. Sweat-Cole and claiming that her implants had deflated or simply had insufficient saline, which placed her at increased risk for surgical and anesthetic complications. These multiple surgeries resulted in continuing deformities, pain, restrictions on activities, and cost. Many of these multiple surgeries could have been avoided if, during the first surgery Clayman Senior had used proper anesthetic and surgical technique with appropriately sized implants determined preoperatively using commonly accepted dimensional planning concepts. Additionally, silicone gel implants should have been offered or at least considered after the first and subsequent surgeries. The benefits of switching to the silicone implants include a lower risk of implant rupture and deflation, as well as a softer, less painful, and more natural feel without rippling compared to overfilled saline implants;

m. By misrepresenting to Ms. Sweat-Cole and others that she had a spontaneous rupture, deflation, or leak at a breast implant. It is unlikely that Ms. Sweat-Cole experienced four (4) separate spontaneous partial deflations of her saline filled implants as described by Loren Z. Clayman, M.D. in a period of 7 years In its follow-up studies, Allergan reports spontaneous saline filled implant deflation rates of 2.7-6.8% at five years, and 10 to 13.8% at 10 years, averaging roughly a risk of 1.2% per year. Based on this information, the odds against Ms. Sweat-Cole experiencing four (4) separate spontaneous deflations over seven (7) years are statistically improbable. Neither the patient photographs nor patient narrative suggest any evidence of implant deflation. A review of the medical literature failed to reveal any published studies or relevant clinical

information regarding multiple spontaneous deflations in the same patient, which underscores how unlikely it would be for such a situation to occur. More likely than not, Ms. Sweat-Cole did not suffer from spontaneous partial deflations of her breast implants;

n. By excessively overfilling her breast implants;

o. By failing to take measures to prevent infectious agents and other materials from contaminating her implants; and

p. By fraudulently concealing, or misrepresenting to Ms. Sweat-Cole and others on one or more occasions that a saline implant had spontaneously deflated, ruptured, or leaked, which caused Ms. Sweat-Cole to conclude that the problems she was having with her breasts were the result of product defects rather than her surgeon's breaches of the applicable standard of care.

64. As a direct and proximate result of above noted breach or breaches of the standard of care by Clayman Senior and/or the Clayman Practice, Ms. Sweat-Cole suffered bodily injury and resulting pain and suffering, mental anguish, disability, disfigurement, and loss of the capacity for the enjoyment of life, has incurred and will incur in the future expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. These losses are permanent or continuing in nature, and she will suffer them in the future.

65. Furthermore, on one or more occasions Clayman Senior and/or employees or agents of the Clayman Practice fraudulently concealed or intentionally misrepresented to Ms. Sweat-Cole and/or others that a saline implant that had been implanted in her body spontaneously deflated, ruptured, or leaked when it/they had not; such fraud, concealment, or intentional misrepresentation caused Ms. Sweat-Cole to conclude that the problems she was

having with her breasts were the result of product defects rather than the result of breaches of the applicable standard of care by Clayman Senior and/or employees or agents of the Clayman Practice.

WHEREFORE, the Plaintiff, **JESSICA LYNN SWEAT-COLE**, demands judgment for damages against the Defendants, **LOREN Z. CLAYMAN, M.D.** and **LOREN Z. CLAYMAN, M.D., P.A.** together with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

COUNT II – CLAYMAN DEFENDANTS' BREACH OF FIDUCIARY DUTY

66. Ms. Sweat-Cole re-alleges and incorporates by reference paragraphs 1 through 60.

67. On or between April 2007 and August 21, 2017, Ms. Sweat-Cole was a patient of Clayman Senior and the Clayman Practice. By virtue of the physician-patient relationship, Clayman Senior and the Clayman Practice had a fiduciary duty to Ms. Sweat-Cole to not perform acts for his/its own pecuniary gain that were contrary to her welfare.

68. Clayman Senior and/or the Clayman Practice violated this fiduciary duty to Ms. Sweat-Cole in one or more of the following ways:

(a). By repeatedly claiming that her breast implants had deflated when in fact they had not.

(b). By repeatedly operating on Ms. Sweat-Cole, which placed her at an increased risk for surgical and anesthetic complications, yet simply repeating the same procedures that were previously performed.

(c). By repeatedly not performing the surgery that her physical condition actually required in favor of surgery that took less time and skill, to save Clayman Senior and/or the Clayman Practice time and money.

(d). By repeatedly operating on her when he/it knew or should have known that he/it did not have the skill or competency to perform the surgeries within the standard of care.

(e). By repeatedly operating on her so that Clayman Senior and/or the Clayman Practice could recover a surgical fee from Allergan each time.

(f). By performing surgery with inadequate anesthesia because it was cheaper, which in turn led to improper implant placement, as well as increased pain, discomfort, and anxiety.

69. Furthermore, on one or more occasions Clayman Senior and/or employees or agents of the Clayman Practice fraudulently concealed or intentionally misrepresented to Ms. Sweat-Cole and/or to others that a saline implant that had been implanted in her body spontaneously ruptured, deflated or leaked, when it had not; such fraud, concealment, or intentional misrepresentation caused Ms. Sweat-Cole to conclude that the problems she was having with her breasts were the result of product defects rather than the result of breaches of the applicable standard of care by Clayman Senior and/or employees or agents of the Clayman Pratctice.

WHEREFORE, the Plaintiff, **JESSICA LYNN SWEAT-COLE**, demands judgment for damages against the Defendants, **LOREN Z. CLAYMAN, M.D.** and **LOREN Z. CLAYMAN, M.D., P.A.** together with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

COUNT III – CLAYMAN DEFENDANTS' FRAUD

70. Ms. Sweat-Cole re-alleges and incorporates by reference paragraphs 1 through 60.

71. On one or more occasions, Clayman Senior and/or employees or agents of the Clayman Practice made the following false statements or representations, which were intended to conceal his/its inability or unwillingness to perform the breast augmentation procedures competently and within the standard of care, and which in fact misled Ms. Sweat-Cole and/or caused her to respond in the following ways to her detriment:

a. In 2009, Clayman Senior told Ms. Sweat-Cole that she had a "pinhole" leak at her left breast implant, and that she needed to have both of her implants removed and replaced. In fact, Ms. Sweat-Cole did not have a leak, rupture, or deflation at her left breast implant, and/or she did not need both of her breast implants removed and replaced. One or more of these representations caused Ms. Sweat-Cole to conclude that the problems she was experiencing with her breasts were not the result of breaches of the standard of care by Clayman Senior and/or employees or agents of the Clayman Practice in the previous surgery, but that she had one or more defective breast implants; one or more of these representations caused her to agree to have another surgery performed by Clayman Senior. As a result, Ms. Sweat-Cole did not seek a second opinion from another plastic surgeon, nor did she seek legal advice for a potential medical negligence claim.

b. In 2010, Clayman Senior told Ms. Sweat-Cole that there was something wrong with her left breast implant, for which he recommended a surgery in which he would remove and replace both of her implants at no charge to her because "Allergan would pay." In fact, she did not have anything wrong with her left breast implant, including a rupture, deflation or leak, and she did not need to undergo a removal and

replacement of both implants as a result. One or more of these representations caused Ms. Sweat-Cole to conclude that the problems she was experiencing with her breasts were not the result of breaches of the standard of care by Clayman Senior and/or employees or agents of the Clayman Practice in the previous surgery, but that she had a defective left breast implant; these representations caused her to agree to have another surgery performed by Clayman Senior. As a result, Ms. Sweat-Cole did not seek a second opinion from another plastic surgeon, nor did she seek legal advice for a potential medical negligence claim.

c. In 2011, Clayman Senior told Ms. Sweat-Cole that "the bag" at her left breast was "leaking," and that she needed to have another surgery to replace both of her implants. In fact, she did not have a rupture, leak or deflation at either of her breast implants, and she did not need to undergo surgery to remove and replace both of her implants. One or more of these representations caused Ms. Sweat-Cole to conclude that the problems she was experiencing with her breasts were not the result of breaches of the standard of care by Clayman Senior and/or employees or agents of the Clayman Practice in the previous surgery, but that she had a defective left breast implant; these representations caused her to agree to have another surgery performed by Clayman Senior. As a result, Ms. Sweat-Cole did not seek a second opinion from another plastic surgeon, nor did she seek legal advice for a potential medical negligence claim.

d. On or about January 27, 2014, Clayman Senior told Ms. Sweat-Cole that her right breast implant "had a leak," and that both of her implants needed to be removed and replaced. In fact, she did not have a rupture, leak or deflation at either of her breast implants, and she did not need to undergo surgery to remove and replace both of her

implants. One or more of these representations caused Ms. Sweat-Cole to conclude that the problems she was experiencing with her breasts were not the result of breaches of the standard of care by Clayman Senior and/or employees or agents of the Clayman Practice in the previous surgery, but that she had a defective left breast implant; these representations caused her to agree to have another surgery performed by Clayman Senior. As a result, Ms. Sweat-Cole did not seek a second opinion from another plastic surgeon, nor did she seek legal advice for a potential medical negligence claim.

e. On or about January 27, 2014, Clayman Senior and/or employees or agents of the Clayman Practice prepared a surgical estimate that stated Ms. Sweat-Cole needed to have a surgical procedure to remove and replace both of her breast implants because her right breast was "smaller." In fact, she did not have a rupture, leak or deflation at either of her breast implants, and she did not need to undergo surgery to remove and replace both of her implants. One or more of these representations caused Ms. Sweat-Cole to conclude that the problems she was experiencing with her breasts were not the result of breaches of the standard of care by Clayman Senior and/or employees or agents of the Clayman Practice in the previous surgery, but that she had a defective left breast implant; these representations caused her to agree to have another surgery performed by Clayman Senior. As a result, Ms. Sweat-Cole did not seek a second opinion from another plastic surgeon, nor did she seek legal advice for a potential medical negligence claim.

f. In the operative report dated April 24, 2014, Clayman Senior documented that she was "found to have a leak at the valve with tissue present and partial delamination of the valve." In fact, she did not have a rupture, leak, or deflation at her

right implant. This representation caused Ms. Sweat-Cole and others to conclude that the problems she was experiencing with her breasts were not the result of breaches of the standard of care by Clayman Senior and/or employees of the Clayman Practice in the previous surgery, but that she had a defective right breast implant; these representations caused her to agree to have subsequent surgeries performed by Clayman Senior rather than seeking second opinions from other plastic surgeons, or seeking legal advice for a potential medical negligence claim.

g. Before the surgery on February 24, 2014, employees or agents of the Clayman practice had Ms. Sweat-Cole sign an Allergan breast implant warranty claim form that stated she had a deflation, rupture, or leak that caused her to have to undergo a removal and replacement surgery. In fact, she did not have a deflation, rupture, or leak at either of her breast implants. This representation caused Ms. Sweat-Cole and others to conclude that the problems she was experiencing with her breasts were not the result of breaches of the standard of care by Clayman Senior and/or employees of the Clayman Practice in the previous surgery, but that she had a defective right breast implant; these representations caused her to agree to have subsequent surgeries performed by Clayman Senior rather than seeking second opinions from other plastic surgeons, or seeking legal advice for a potential medical negligence claim.

72. As a result of the above false statements or representations, Clayman Senior and and/or the Clayman Practice were able to continue collecting money in relation to the medical and surgical care of Ms. Sweat-Cole, Ms. Sweat-Cole did not seek a second opinion from another plastic surgeon, and/or Ms. Sweat-Cole delayed seeking legal counsel for potential medical negligence.

73. As a direct and proximate result of the above noted false statements or representations of Clayman Senior and/or employees or agents of the Clayman Practice, Ms. Sweat-Cole suffered bodily injury and resulting pain and suffering, mental anguish, disability, disfigurement, and loss of the capacity for the enjoyment of life, has incurred and will incur in the future expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. These losses are permanent or continuing in nature, and she will suffer them in the future.

WHEREFORE, the Plaintiff, **JESSICA LYNN SWEAT-COLE**, demands judgment for damages against the Defendants, **LOREN Z. CLAYMAN, M.D.** and **LOREN Z. CLAYMAN, M.D., P.A.** together with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

COUNT IV – CLAYMAN DEFENDANTS' AND ALLERGAN'S CONSPIRACY TO COMMIT BREACH OF FIDUCIARY DUTY AND/OR FRAUD

74. Ms. Sweat-Cole re-alleges and incorporates by reference paragraphs 1 through 60, 67, 68, 71, and 72.

75. On or before April 1, 2007, Clayman Senior, the Clayman Practice, and/or Elana Clayman entered into an agreement with Allergan to commit one or more breaches of a fiduciary duty and/or fraud in relation to the patients of the Clayman practice. The following acts and conduct are illustrative of the parties' intent to enter this agreement:

a. The Claymans sending removed breast implants and warranty claim paperwork to Allergan, signed by both the patient and Clayman Senior, stating that the patient had a rupture, deflation, or leak that required a removal and replacement surgery, and assigning the benefits of the warranty claim to the Claymans;

b. Allergan sending the Claymans a check for the Surgery Money despite the fact that its "Laboratory Analysis" on the returned breast implants found no evidence of a loss of shell integrity, resulting in implant rupture or deflation;

c. Allergan further demonstrating its assent to the agreement by repeating its conduct (paying warranty claims for saline breast implants that Allergan knew did not demonstrate a loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention) at least 809 times before January 1, 2010;

d. Allergan receiving, as consideration for its payment of the Surgery Money, the Claymans' purchase of large quantities of breast implants, medical devices, and pharmaceuticals from Allergan.

76. Allergan, through its employees or agents, knew that Clayman Senior and/or the Clayman Practice were breaching a fiduciary duty owed to Ms. Sweat-Cole, and/or committing fraud upon her as well, due to the following:

(a). At the time that Allergan paid the warranty claim in relation to the February 24, 2014 implant removal and replacement surgery, Allergan had received more than 3,843 warranty claims from the Clayman Practice for saline breast implants that Allergan knew did not demonstrate a "loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention";

(b). Allergan's *Laboratory Analysis* report for the right saline filled breast implant that was implanted by Clayman Senior into Ms. Sweat-Cole in 2011, and explanted by Clayman Senior on February 24, 2014, did not demonstrate a "loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention," and, thus, the February 24, 2014 surgery was not necessary as a result of a failed breast

implant;

(c). The rate of ruptures, deflations, or leaks of Natrelle saline filled implants claimed by the Clayman Practice was markedly higher than the rate shown by Allergan's own studies for Natrelle saline filled implants.

77. Allergan committed one or more of the following overt acts in furtherance of the conspiracy to breach a fiduciary duty and/or to commit fraud:

(a). Continuing to sell saline breast implants to the Claymans after 2009, even though Allergan had already received more than 809 warranty claims from the Clayman Practice for saline breast implants that Allergan knew did not demonstrate a "loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention";

(b). Paying the Clayman Practice's warranty claim, without requesting further corroboration, in relation to the right saline breast implant that Clayman Senior placed into Ms. Sweat-Cole in 2011, and which Clayman Senior surgically removed on February 24, 2014;

(c). Paying the Clayman Practice's warranty claim in relation to the right saline breast implant that Clayman Senior placed into Ms. Sweat-Cole in 2011, and which Clayman Senior surgically removed on February 24, 2014, even though Allergan had already received more than 3,843 warranty claims from the Clayman Practice knew did not demonstrate a loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention; and

(d). Continuing to sell saline breast implants to the Clayman Practice after 2014 even though Allergan had already received more than 4,900 warranty claims for saline breast implants from the Clayman Practice that Allergan knew did not demonstrate

a “loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention.

78. On or before February 24, 2014, through her work as the office manager of the Clayman Practice, Elana Clayman knew that Clayman Senior and/or the Clayman Practice were breaching a fiduciary duty owed to Ms. Sweat-Cole, and/or committing fraud upon her as well, due to the following:

a. The rate of ruptures, deflations, or leaks of Natrelle saline filled implants claimed by the Clayman Practice was markedly higher than the rates of ruptures, deflations, or leaks that saline breast implants typically experience for a similar number of patients;

b. The Clayman Practice’s warranty claims to Allergan were fraudulent because they were for saline breast implants that had not actually experienced ruptures, deflations, or leaks; and

c. The Clayman Practice’s breast implant patients were undergoing breast implant revision surgeries that were not necessary as a result of ruptures, deflations, or leaks of their saline breast implants.

79. On or between April 1, 2007 and August 21, 2017, Elana Clayman committed one or more of the following overt acts in furtherance of the conspiracy to breach a fiduciary duty and/or to commit fraud:

a. depositing the Surgery Money received from Allergan into a separate bank account or accounts controlled in whole or in part by Elana Clayman;

b. managing the accounting of the separate bank account or accounts that held the Surgery Money in separate bookkeeping ledgers or systems controlled in whole or in part by Elana Clayman; and

c. managing the Surgery Money separately from other income received by the Clayman Practice so that the Surgery Money would not be treated as taxable income by the Internal Revenue Service, the Florida Department of Revenue, or any other governmental agency.

80. As a direct and proximate result of the above noted conspiracy to commit fraud and/or breach of fiduciary duty by Clayman Senior, the Clayman Practice, Elana Clayman, and Allergan, Ms. Sweat-Cole suffered bodily injury and resulting pain and suffering, mental anguish, disability, disfigurement, and loss of the capacity for the enjoyment of life, has incurred and will incur in the future expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. These losses are permanent or continuing in nature, and she will suffer them in the future.

81. Furthermore, as a direct and proximate result of the above noted conspiracy to breach a fiduciary duty and/or to commit fraud by Clayman Senior, the Clayman Practice, Elana Clayman, and Allergan, Ms. Sweat-Cole has spent monies in the amount of $3,750 or more, for medical and/or surgical care by the Clayman Practice that was of no value, and which has caused her to have to incur future medical expenses to correct the damages done by said medical and/or surgical care.

WHEREFORE, the Plaintiff, **JESSICA LYNN SWEAT-COLE**, demands judgment for compensatory damages against the Defendants, **LOREN Z. CLAYMAN, M.D.**, **LOREN Z. CLAYMAN, M.D., P.A., ELANA CLAYMAN,** and **ALLERGAN SALES, LLC,** together

with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

ALLERGAN AND ELANA CLAYMAN AIDING AND ABETTING THE CLAYMAN PRACTICE'S BREACH OF FIDUCIARY DUTY AND/OR FRAUD

82. Ms. Sweat-Cole re-alleges and incorporates by reference paragraphs 1 through 60, 67, 68, 71, and 72.

83. Allergan, through its employees or agents, knew that Clayman Senior and/or the Clayman Practice was/were breaching a fiduciary duty owed to Ms. Sweat-Cole, and committing fraud upon her as well, due to the following:

(a). At the time that Allergan paid the warranty claim in relation to the February 24, 2014 implant removal and replacement surgery, Allergan had received more than 3,843 previous warranty claims from the Clayman Practice for saline breast implants that Allergan knew did not demonstrate a "loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention";

(b). Allergan's *Laboratory Analysis* report for the right saline filled breast implant that that was surgically removed from her by Clayman Senior on February 24, 2014, did not demonstrate a "loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention," and, thus, the February 24, 2014 surgery was not necessary as a result of a failed breast implant; and

(c). By February 24, 2014, the rate of ruptures, deflations, or leaks for patients with Natrelle saline filled implants claimed by the Clayman Practice was markedly higher than the rate shown by Allergan's own studies for Natrelle saline filled implants.

84. Despite the aforesaid knowledge of Allergan through its employees or agents, Allergan provided substantial assistance to Clayman Senior and/or the Clayman Practice in committing fraud against, and/or breaching a fiduciary duty owed to, Ms. Sweat-Cole in one or more of the following ways:

(a). Continuing to sell saline breast implants to the Claymans after 2009, even after Allergan had already received more than 809 warranty claims from the Claymans Practice for saline breast implants that Allergan knew did not demonstrate a "loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention";

(b). Paying the warranty claim of the Clayman Practice and/or Clayman Senior, without requesting further corroboration, in relation to the right saline filled breast implant that Clayman Senior placed into Ms. Sweat-Cole in 2011, and which Clayman Senior surgically removed on February 24, 2014; and

(c). Paying the Clayman Practice's warranty claim in relation to the right saline breast implant that Clayman Senior placed into Ms. Sweat-Cole in 2011, and which Clayman Senior surgically removed on February 24, 2014, even though Allergan had already received more than 3,843 warranty claims from the Clayman Practice that Allergan knew did not demonstrate a loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention

(d). Continuing to sell saline breast implants to the Clayman Practice after 2014 even though Allergan had already received more than 4,900 warranty claims for saline breast implants from the Clayman Practice that Allergan knew did not demonstrate a "loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention.

85. On or before February 24, 2014, through her work as the office manager of the Clayman Practice, Elana Clayman knew that Clayman Senior and/or the Clayman Practice were breaching a fiduciary duty owed to Ms. Sweat-Cole, and/or committing fraud upon her as well, due to the following:

a. The rate of ruptures, deflations, or leaks of Natrelle saline filled implants claimed by the Clayman Practice was markedly higher than the rates of ruptures, deflations, or leaks that saline breast implants typically experience for a similar number of patients;

b. The Clayman Practice's warranty claims to Allergan were fraudulent because they were for saline breast implants that had not actually experienced ruptures, deflations, or leaks; and

c. The Clayman Practice's breast implant patients were undergoing breast implant revision surgeries that were not necessary as a result of ruptures, deflations, or leaks of their saline breast implants.

86. On or between November February 24, 2014, and August 21, 2017, Elana Clayman committed one or more of the following overt acts in furtherance of the conspiracy to breach a fiduciary duty and/or to commit fraud:

a. depositing the Surgery Money received from Allergan into a separate bank account or accounts controlled in whole or in part by Elana Clayman;

b. managing the accounting of the separate bank account or accounts that held the Surgery Money in separate bookkeeping ledgers or systems controlled in whole or in part by Elana Clayman; and/or

c. managing the Surgery Money separately from other income received by the Clayman Practice so that the Surgery Money would not be treated as taxable income by the Internal Revenue Service, the Florida Department of Revenue, or any other governmental agency.

87. As a direct and proximate result of the substantial assistance provided by Allergan and Elana Clayman to Clayman Senior and/or the Clayman Practice, Ms. Sweat-Cole suffered bodily injury and resulting pain and suffering, mental anguish, disability, disfigurement, and loss of the capacity for the enjoyment of life, has incurred and will incur in the future expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. These losses are permanent or continuing in nature, and she will suffer them in the future.

88. Furthermore, as a direct and proximate result of the above noted substantial assistance provided by Allergan and Elana Clayman to Claymans Senior and/or the Clayman Practice, Ms. Sweat-Cole has spent monies in the amount of $3,750 or more, for medical and/or surgical care by the Clayman Practice that was of no value, and which has caused her to have to incur future medical expenses in the future to correct the damages done by said medical and/or surgical care.

WHEREFORE, the Plaintiff, **JESSICA LYNN SWEAT-COLE**, demands judgment for compensatory damages against the Defendants, **LOREN Z. CLAYMAN, M.D., LOREN Z. CLAYMAN, M.D., P.A., ELANA CLAYMAN** and **ALLERGAN SALES, LLC,** together

with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

/s/ Christopher Shakib_____
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